

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION)	
and BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
Plaintiffs,)	C.A. No. 05-768 (SLR)
)	
v.)	
)	
CONOR MEDSYSTEMS, INC.,)	
)	
Defendant.)	

CONOR'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STAY

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INTRODUCTION

Defendant Conor Medsystems, Inc. (“Conor”) submits this reply brief in support of its motion to stay this case pending resolution of the related Jang Ownership Litigation.

There is no dispute that BSC’s ownership of the patent-in-suit is uncertain. Almost ten months ago, the named inventor of the ‘021 patent sued BSC to rescind the assignment agreement that is the only source of BSC’s rights to the ‘021 patent. Absent that assignment, BSC does not have standing to maintain this action. Unless this lawsuit is stayed pending resolution of the Jang Ownership Litigation, the Court and the parties face the very real possibility that this case will be litigated for a year only to be dismissed for BSC’s lack of standing.

The risk of dismissal provides a compelling reason to stay this action. In its brief, BSC has presented no similarly compelling reason to proceed. In fact, the arguments made, and not made, by BSC prove that a stay should be granted.

First, given the posture of this case (which has just started, in which there is no scheduling order, and in which there has been no discovery) and the Jang Ownership Litigation (which was filed months before this lawsuit and which is set for trial in February 2007), a stay will preserve the resources of this Court. This case raises numerous issues that were never litigated in the *Cordis* Action. Moreover, this lawsuit will be hotly contested on all fronts – noninfringement, invalidity, and unenforceability. A stay will prevent this Court from expending its time and resources on a complex case that will disappear from its docket if Dr. Jang prevails in his ownership challenge in California.

Second, the public interest does not favor proceeding with this case. To the contrary, and as BSC itself admitted when it opposed Cordis’s preliminary injunction motion, the

public interest favors allowing competing medical devices onto the market. There is little public interest in preventing effective coronary stents from reaching patients and physicians.

Third, a stay will not prejudice BSC. BSC's argument is premised on the notion that it is somehow entitled to a trial on the merits before Conor launches its stent in the United States. Even if a stay were not entered, there is no guarantee that BSC could proceed to trial against Conor before Conor receives FDA approval. BSC's other argument – that having Conor's stents on the market might somehow "taint" BSC – is unfounded, because Conor intends to show that its CoStar stent is as safe and effective as BSC's Taxus stent through Conor's ongoing clinical trial.

Finally, proceeding with this case will prejudice Conor. If Dr. Jang prevails in his ownership lawsuit and the assignment to BSC is rescinded, Conor will have wasted money, management time, and other resources litigating this case against BSC. Moreover, because Dr. Jang cannot take over as plaintiff in this case in the event that BSC lacks standing, and because Dr. Jang may decide not to file a new lawsuit (in Delaware or elsewhere) against Conor, the risk of waste is enormous.

ARGUMENT

In its Answering Brief (D.I. 19), BSC does not dispute that if the Central District of California rescinds the assignment of the '021 patent to BSC in the Jang Ownership Litigation, this case must be dismissed for lack of standing. Nevertheless, BSC argues that "there is **no chance** that a stay pending resolution of the Contract Action will **simplify any liability issues** for trial." D.I. 19 at 7-8 (emphasis supplied). This argument is baseless.

A finding that BSC does not own the '021 patent would necessarily and immediately cause a drastic simplification of issues, because this action would have to be dismissed in its entirety. *See, e.g., Lans v. Gateway 2000, Inc.*, 84 F. Supp. 2d 112, 123 (D.D.C.

1999) (where a patentee had lost title to the patent, he also had “lost standing to sue on any infringement of the patent. This lack of standing is a defect in the Court’s jurisdiction over this case and thus mandates its dismissal.”), *aff’d*, 252 F.3d 1320 (Fed. Cir. 2001).

This District recently has recognized the efficiency of staying a patent infringement case pending resolution of an action challenging the plaintiff’s ownership of the patent. In *St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elec. Co., Ltd.*, Civil Action No. 04-1436-JJF (D. Del. Feb. 14, 2006) (Exh. E), St. Clair sued a number of defendants for patent infringement. St. Clair and a third party then became involved in litigation over ownership of the patents-in-suit. The defendants moved for a stay pending resolution of the ownership issue. Judge Farnan granted a stay, stating:

The Court concludes that a stay is appropriate for several reasons. First, discovery has not begun. Second, a stay will allow the ownership issue to be resolved in the [ownership] action without the complications of other Defendants. Finally, Plaintiff will not be unduly prejudiced by the granting of the stay. The stay may well save time and expense, not only for Defendants, but for Plaintiff.

Id. at 4. The same reasoning applies here. Discovery has not begun, a stay will permit the California court to resolve the Jang Ownership Litigation, BSC will not be prejudiced, and both Conor and BSC (and the Court) may well save time and expense.¹

¹ BSC appears to argue that only where an infringement defendant asserts rights to the patent-in-suit should a case be stayed pending resolution of ownership. D.I. 19 at 7-8 (discussing *Wing Shing Products, Summa Four, Santrade*, and *Loral Fairchild*). As an initial matter, BSC misapprehends the *Loral Fairchild* decision. None of the infringement defendants in that case sought a stay pending a litigation to determine whether it was a licensee. More importantly, a lack of patent ownership destroys the plaintiff’s standing irrespective of the defendant’s other defenses. *See Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (only a valid assignment “confers constitutional standing on the assignee to sue another for

(continued)

As shown below, BSC's various arguments against a stay are without merit.

A. A Stay Will Serve The Court's Interest In Efficient Resolution Of Disputes

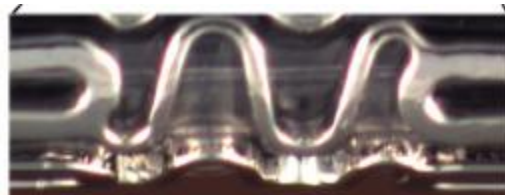
1. This Case Raises Different Issues Than The Cordis Action

BSC argues that this case should proceed because the issues raised are easy, will not require significant judicial resources, and are familiar to the Court from the *Cordis* Action. D.I. 19 at 3, 4, 9. The Court's experience with the '021 patent and with stent litigation in general, however, clearly shows that this case will not be easy, will be vigorously litigated, and will consume significant judicial resources.

BSC tells the Court that "many of the issues likely to arise in this action have already been addressed by this Court in the *Cordis* Action." D.I. 19 at 9. In doing so, BSC reaches too far. Most of the defenses in Conor's Answer were never litigated in the *Cordis* Action, including inequitable conduct and exemption from infringement under 35 U.S.C. § 271(e)(1). Regarding invalidity, Conor intends to make a number of anticipation and obviousness arguments that were not made by Cordis. For example, Figure 11 of U.S. Patent No. 5,807,404 to Richter predates the '021 patent and discloses an N-shaped connector substantially identical to the N-shaped connector accused in the *Cordis* Action:



Portion of Fig. 11 of U.S. Pat. No. 5,807,404



Accused Cordis Stent

(continued)

patent infringement in its own name"); *Monsanto Co. v. Aventis Cropscience SA*, 2001 U.S. Dist. LEXIS 8891, at *16 (D. Del. 2001) (same).

To the extent the '021 claims read upon the Cordis stent, as BSC asserts, those claims are anticipated by the disclosure of Richter. Moreover, Dr. Jang and his prosecuting attorney were aware of, but failed to disclose to the Examiner, the Richter patent during prosecution of the '021 patent, thus raising serious issues of inequitable conduct. Cordis did not raise these issues.

BSC also tells the Court that "Conor's stent design presents an easier infringement analysis than the one implicated by the stents already found to be infringing in the Cordis Action." D.I. 19 at 4. But BSC has not identified which claims it asserts are infringed and its "infringement analysis" is limited to only one limitation – "corners" – with no suggestion that Conor's products meet any of the many remaining limitations of the claims.² It is fundamental to patent law that for a device to infringe a patent, it must meet each limitation of a claim. *See Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) ("To prove literal infringement, the patentee must show that the accused device contains every limitation in the asserted claims. If even one limitation is missing or not met as claimed, there is no literal infringement.") (citation omitted).

A more thorough analysis demonstrates the weakness of BSC's infringement case. Claim 36 of the Jang '021 patent requires not just any "corner," but a corner formed where a joining strut is coupled to an expansion strut and a connecting strut.

² The Jang '021 patent has 85 claims. Claim 36, asserted against Cordis, along with claim 23 from which it depends, covers almost two entire columns of text.



Conor's CoStar Stent

An examination of the Conor stent proves that it does not possess such a corner. In addition, there will be disputes as to whether Conor's stents meet many other limitations, including whether it has the "joining strut," the "connecting strut," the "first connecting strut intermediate section," etc. set forth in claim 36 and other claims.

2. BSC Mischaracterizes The Jang Ownership Lawsuit

BSC asserts that a stay should be denied because there is "only a minimal chance that Dr. Jang will obtain ownership of the Jang '021 patent." D.I. 19 at 12. This self-serving and premature assessment of the merits of Dr. Jang's claim should be given no weight – especially because discovery in the Jang Ownership Lawsuit has not concluded and BSC provides no facts or law to support its position. Dr. Jang's complaint presents a cogent claim that the assignment of the '021 patent should be rescinded for fraud, non-payment, and mistake. Exh. B [Jang Complaint] ¶¶ 32-33. BSC has not moved for dismissal or summary adjudication of that claim, and it remains before the California court. As such, BSC's prediction that it is "unlikely to lose any rights to the Jang '021 patent" (D.I. 19 at 8) should be taken with a grain of salt. Moreover, courts have granted stays to await resolution of ownership disputes that, on their face, were less likely to divest a plaintiff of its ownership rights in a patent. In *Wing Shing Prods. (BVI) Ltd. v. Simatelex Manufactory Co.*, 2005 U.S. Dist. LEXIS 6780, at *2 (S.D.N.Y. 2005), for example, the court granted a stay to await the losing party's appeal of a trial court's determination that the

plaintiff did own the patent-in-suit – a procedural posture far less likely to result in loss of ownership than Jang’s claim for rescission.

BSC’s attempt to downplay Dr. Jang’s demand to rescind the ‘021 patent assignment as “merely ... an alternative form of relief” is misleading. D.I. 19 at 8. Dr. Jang’s complaint expressly seeks rescission of the assignment of the ‘021 patent because of nonpayment, fraud, and mistake. Exh. B [Jang Complaint] ¶¶ 30-34. BSC acknowledges this fact in its SEC filings, where it describes Dr. Jang as “seeking monetary damages and rescission [sic] of the contract.” Exh. D [BSC 10K] at 20. Moreover, BSC’s assessment is plainly contradicted by a January 17, 2006 letter from Dr. Jang to BSC. Exh. F [January 17, 2006 letter from Jang to BSC]. The letter states: “For reasons known only to your clients, they elected to ... initiate the Conor litigation with full knowledge of Dr. Jang’s rescission of the assignment agreement.” *Id.* BSC’s assertion that Dr. Jang “primarily seeks monetary damages” (D.I. 19 at 8) is similarly contradicted by the January 17 letter, which claims, no less than five times, that the assignment to BSC of Dr. Jang’s patents should be rescinded.

B. The Public Interest Does Not Favor Proceeding With This Lawsuit

BSC argues that the public interest favors proceeding with this litigation in order to prevent Conor’s stent from ever entering the market.³ D.I. 19 at 9-10. This argument fails for at least two reasons.

First, BSC’s argument assumes that the ‘021 patent is valid, enforceable, and

³ BSC disparages the stay requested by Conor as “immoderate and indefinite.” D.I. 19 at 9. It is neither – Conor seeks a stay pending resolution of the Jang Ownership Litigation, currently scheduled for trial in February 2007. Moreover, as a party to the California lawsuit, BSC is well positioned to ensure that the litigation runs efficiently and that the trial date is maintained.

infringed – each of which Conor vigorously disputes. Second, the public interest is harmed by denying doctors and patients the use of effective medical devices. *See, e.g., Cordis Corp. v. Boston Scientific Corp. & SciMed Life Sys., Inc.*, Case Nos. 03-027-SLR, 03-283-SLR, 2003 U.S. Dist. LEXIS 21338, at *6 (D. Del. 2003) (noting the “obvious concern of depriving the public of the best and safest medical devices by limiting competition”), *aff’d*, 99 Fed. Appx. 928, 935 (Fed. Cir. 2004) (unpublished) (“a strong public interest supports a broad choice of drug-eluting stents”); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (affirming denial of motion for preliminary injunction when the “public [would] be harmed by an injunction in that some physicians prefer defendant’s dual lumen IABs”). Conor’s products have been recognized as effective outside the United States,⁴ and Conor intends to show that its stents are as effective as BSC’s Taxus stent in connection with its ongoing U.S. clinical trial.⁵ Thus, the public interest favors allowing the Conor stents on the market.

The public interest arguments in BSC’s brief are particularly surprising given that BSC argued exactly the **opposite** to this Court in the *Cordis* Action. In its response to a Cordis motion for preliminary injunction, BSC highlighted the “public’s interest in a competitive medical device market that **allows patients and health care professionals to choose the safest and most effective treatment possible in each case.**” Exh. H at 14 [Defendants’ Preliminary Response to Plaintiff’s Motion for a Preliminary Injunction, dated March 14, 2003] (emphasis added). BSC also relied on *Scripps Clinic & Research Found. v Genentech, Inc.*, 666 F. Supp. 1379, 1401 (N.D. Cal. 1987), *aff’d-in-part, rev’d-in-part*, 927 F.2d 1565 (Fed. Cir. 1991), which,

⁴ Exh. G [Conor Feb. 17, 2006 press release].

⁵ Hacker Reply Decl. ¶ 3.

in BSC's words, "found that the public has an interest in access to the best possible medical treatments." *Id.* Perhaps most revealing, BSC argued in the *Cordis* Action that barring the sale of its stents from the market would deprive patients and doctors of the ability to choose the best medical treatment:

This Court has recognized "the public's interest in a competitive medical device market." That interest is best served by letting patients and their healthcare professionals evaluate CYPHER, TAXUS and the available bare-metal stents and choose the safest and most effective stent possible in each case. Cordis seeks to eliminate that choice, without a trial on the merits, to increase its profits. That is not in the public interest.

Id. at 17.

In short, BSC's position in the *Cordis* Action is consistent with Conor's position here – that the public interest is not served by BSC's attempt to prevent the public and physicians from using Conor's stents.⁶ *Bionx Implants, Inc. v. Innovasive Devices, Inc.*, 45 F. Supp. 2d 75, 79 (D. Mass. 1999) (denying motion for preliminary injunction in part because "the public interest overall will be served by leaving the medical community to sort out which device is better under which circumstances").

C. BSC's Allegations Of Harm Are Without Merit

The primary harm about which BSC complains is that a stay allegedly will prevent BSC from getting a permanent injunction before commercial launch of Conor's stent in the United States. D.I. 19 at 11. As an initial matter, this alleged harm presumes that BSC can

⁶ BSC also argues that "[a]llowing Conor to launch the infringing CoStar stents in the United States, only to be forced to pull those stents off the market once this case is tried on the merits, would harm the public interest by disrupting hospitals and forcing doctors and patients to scramble unnecessarily." D.I. 19 at 10. This argument is baseless and BSC cites no evidence to support it.

get the trial schedule it wants. The Court's schedule controls the timing of this case, not BSC's competitive priorities. Moreover, regardless of whether a stay is granted or denied, BSC's position is highly speculative.

On the one hand, if the Court were to deny a stay, BSC still might not be in a position to seek an injunction before Conor's stents are launched in the United States. BSC's argument presumes that this litigation will progress rapidly, that BSC will win on the merits, and that the Court will promptly enjoin sales of Conor's CoStar stent. As BSC knows from the *Cordis* Action, stent infringement litigation can last many years. Moreover, there may be a delay between an infringement verdict and an injunction, if one is entered at all – JMOL and new trial motions are presently before the Court in the *Cordis* Action and the possibility of appeal remains.

On the other hand, if the Court were to enter a stay and BSC were to prevail against Dr. Jang, BSC still might get to trial before Conor commercially launches its stents in the United States. FDA clearance and product launch are uncertain: "the process of securing FDA approval for a new medical product can be tortuously extended and riddled with unpredictabilities." *Intermedics v. Ventritex, Co.*, 775 F. Supp. 1269, 1275 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (unpublished). In Conor's case, the FDA could require submission of more or different data, the enrollment of more patients, a change to the design of Conor's stent, or even refuse approval of Conor's device. As such, a stay may have no impact on BSC's hope for a permanent injunction before commercial launch.

BSC also complains that granting a stay would force BSC to seek a rushed and burdensome preliminary injunction after the trial in the Jang Ownership Litigation to prevent the

launch of Conor's stent and protect the reputation of BSC's Taxus stent. D.I. 19 at 11. This harm is illusory for at least two reasons.

First, Conor will not be manufacturing stents in the United States at the time that BSC envisions it would need to move for a preliminary injunction (February 2007). Instead, Conor will be pursuing its clinical trial in the United States. Because all of Conor's activities in the United States will be reasonably related to seeking FDA approval, they "are protected by § 271(e)(1)" and BSC will not be suffering "any legally cognizable harm as a result of defendants' conduct." *Intermedics*, 775 F. Supp. at 1276. Where a company's conduct is protected by § 271(e)(1), a preliminary injunction is properly denied on the grounds it seeks an impermissible advisory opinion. *Telectronics Pacing Sys, Inc. v. Ventitrex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992) (affirming dismissal for a lack of controversy where accused device had not received FDA clearance and changes were still possible). Moreover, any financial interest BSC may have in entry of a pre-launch injunction is trumped by the public's interest in access to the best possible health care. *Intermedics*, 775 F. Supp at 1276-77 (by enacting § 271(e)(1), "Congress elevated the health care interests of the public above the pecuniary interests of the patent holders"). When Conor does eventually receive FDA clearance for its stent, BSC "can revive its patent infringement claims and have the issue of infringement decided on the merits." *Id.* at 1289.

Second, BSC's concern that sales of its Taxus stent could be negatively impacted if "the CoStar stent harms any patients or turns out to be an inferior stent" is unfounded. D.I. 19 at 11. In fact, it is more likely that BSC's real concern is that the superiority of the CoStar product will negatively impact BSC's sales of Taxus. In any event, it is the FDA's role to ensure that the CoStar stent is safe, effective, and not inferior to the Taxus stent.

D. Allowing This Case To Proceed Risks Significant Prejudice To Conor

Absent a stay, both the Court and Conor face the very real possibility that this case will be litigated for a year only to be dismissed for BSC's lack of standing. *Lans v. Gateway 2000, Inc.*, 84 F. Supp. 2d at 123. If dismissal occurs, all of the Court's and Conor's efforts would be irrevocably wasted because Jang, even if he wanted to sue Conor in Delaware,⁷ cannot be substituted into this action. *Arrow Drilling Co. v. Carpenter*, 2004 U.S. Dist. LEXIS 4632 (E.D. Pa. 2004) ("Plaintiffs may not amend their complaint to add new plaintiffs in order to cure a lack of subject matter jurisdiction."), *aff'd*, 125 Fed. Appx. 423 (3d Cir. 2005) (unpublished); *Fox v. Board of Trustees of State Univ. of N.Y.*, 148 F.R.D. 474, 486 (N.D.N.Y. 1993) ("Rule 21 cannot be employed as a means to create a case or controversy through substitution where one no longer exists."). BSC's brief simply ignores this harm.

Instead, BSC argues that "the chance that Conor will face a separate lawsuit from Dr. Jang for infringement of the Jang '021 patent is nonexistent because BSC and Dr. Jang are in privity for purposes of *res judicata*." D.I. 19 at 12 (emphasis supplied). This assurance of privity is a red herring because, even assuming privity existed, there is unlikely to be a final decision in this case before the trial in the Jang Ownership Litigation. It is black letter law that protection of Conor by *res judicata* requires: (1) an earlier decision on an issue; (2) a final decision on the merits; and (3) the involvement of the same parties, or parties in privity with the original parties. Restatement (Second) of Judgments §§ 13, 41 (1982); *Allen v. McCurry*, 449

⁷ BSC's argument that "[t]he only question is when, not if, the present infringement allegations against Conor will be adjudicated" by this Court is speculative and wrong. D.I. 19 at 8. If Dr. Jang regains ownership of the '021 patent, he may license the '021 patent to Conor, he may sue Conor elsewhere, or he may not sue Conor at all, each of which would conserve this Court's resources.

U.S. 90, 94 (1980). Because the Jang Ownership Litigation is scheduled for trial in February 2007, there will be no earlier decisions on any issues nor a final decision on the merits from this action. As such, even if privity between BSC and Jang does exist now (which it does not), there will be no *res judicata* effect from this litigation to protect Conor from subsequent allegations of infringement of the '021 patent.

CONCLUSION

Conor respectfully requests that this Court stay this action pending resolution of the Jang Ownership Litigation.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 6, 2006, he caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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